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EXHIBIT 1

AUG 2 6 2004 **510(k) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K040580

1. **Submitter's Identification:**

D.Y. Instrument, Inc.
30 Manning Lane
Cherry Hill, NJ 08003

Contact: Dr. Young H. Lee, President

Date Summary Prepared: May 30, 2004

2. **Name of the Device:**

AIS100 Automatic Intramuscular Stimulator

3. **Predicate Device Information:**

K024207, Vinco Brand Acupuncture Needle

4. **Device Description:**

The AIS 100 is an intramuscular stimulator device that aids administering of intramuscular stimulation (or dry needling) for treatment. The device produces an automated forward and backward motion of a needle at a constant speed, which replaces the manual stroking of a needle when rendering the intramuscular stimulation (or dry needling) treatment. This enables the practitioner to administer the intramuscular stimulation treatment effectively with less physical effort when compared to the manual method. The device consists of a main control unit, a hand-held motor unit, and an AC power supply adapter.

5. **Intended Use:**

The DY Instrument, Inc. AIS100 Automatic Intramuscular Stimulator Device is intended, as part of a treatment regimen, for

1. Intramuscular stimulation
2. Symptomatic relief of tension-type headache of myofascial origin

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6. **Comparison to Predicate Devices:**

The needle used with the AIS100, the TECA EMG needle (K973442), is equivalent to the predicate, Vinco Acupuncture Needle (K024707), in terms of physical dimension - diameter, length, and tip shape; and material of construction - stainless-steel. Both needles are FDA-cleared, supplied in sterile packages, and have handles for manual handling. The needling technique used with the AIS100 is equivalent to one of the needling techniques used with the predicate device in the practice of acupuncture in terms of initial insertion method, the use of short multiple strokes, the shortness of stroke length, and the needling termination method.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:**

Non-clinical performance testing included:

- IEC 60601-1
- IEC 60601-1-2

8. **Discussion of Clinical Tests Performed:**

Human clinical studies were conducted using the AIS100 Automatic Intramuscular Stimulator device to demonstrate the safety of the subject device and the intramuscular stimulation procedure in treating chronic or recurrent pain by measuring any and all adverse effects of the procedure administered using the subject device.

To demonstrate the efficacy of the intramuscular stimulation (IMS) procedure using the AIS100 in the treatment of chronic or recurrent pain, particularly the tension-headache, efficacy was measured in terms of pain recurrence and pain relief using a pain scale and range of motion of the cervical spine. The impact upon quality of life was also evaluated using the pain disability index.

A prospective study of 28 individuals with tension-type headaches of at least 2 months' duration was conducted. Patients had received various other forms of treatment or no treatment at all before entering the study. The patients received a total of five treatments over a 10 week period, with each treatment consisting of myofascial release therapy (15 mins), IMS treatment using the AIS100 (30-45 mins), hot packs (10 mins), and AquaMED (15 mins). After the first treatment, 71.4% of the patients experienced relief for 72 hrs or more, and after two treatments, 64.3% of patients experienced a 50% decrease in their level of pain. Flexion, extension, and lateral flexion range of motion improvements were also statistically significant after five treatments. Finally, patients experienced a statistically significant improvement in all seven categories of the pain disability/lifestyle index. No adverse effects have been observed.

The IMS technique using the Automatic Intramuscular Stimulator device AIS100 appears to be an effective treatment for relieving the pain associated with

tension-type headaches.

9. Conclusions:

The AIS100 Automatic Intramuscular Stimulator has similar intended uses and similar characteristics as the predicate device. Moreover, bench testing contained in this submission and human clinical testing supplied demonstrate that any differences in their technological characteristics or modes of operations do not raise any new questions of safety or effectiveness. Thus, the AIS100 Automatic Intramuscular Stimulator is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2004

Dr. Young H. Lee
President
D.Y. Instrument, Incorporated
30 Manning Lane,
Cherry Hill, New Jersey 08003

Re: K040580
Trade/Device Name: AIS100 Automatic Intramuscular Stimulator
Regulation Number: 880.5580
Regulation Name: Acupuncture Needle
Regulatory Class: II
Product Code: NRW
Dated: August 23, 2004
Received: August 24, 2004

Dear Dr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040580

Exhibit B

510(k) Number (if known): K040580

Device Name: AIS100 Automatic Intramuscular Stimulator

Indications For Use:

The D.Y. Instrument, Inc. AIS100 Automatic Intramuscular Stimulator Device is intended, as part of a treatment regimen, for

1. Intramuscular stimulation
2. Symptomatic relief of tension-type headache of myofascial origin

Prescription Use __X____ **Over-The Counter Use** ____

(Per 21 CFR 801 Subpart D) **OR** **(21 CFT 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040580